

Adult CIRB - Early Phase Emphasis Meeting Agenda

April 7, 2026

I New Study - Initial Review

10743, Pilot Phase II Trial Evaluating Safety and Feasibility of Neoadjuvant Botensilimab and Balstilimab in Clear Cell Renal Cell Carcinoma (NEO RoBOT) (Version Date 03/10/26)

II Continuing Review

A071401, Phase II Trial of SMO/AKT/NF2/CDK Inhibitors in Progressive Meningiomas with SMO/AKT/NF2/CDK Pathway Mutations (Version Date 01/06/26)

III Continuing Review

9825, A Phase 2 Study of Olaparib and Cediranib for the Treatment of Recurrent Ovarian Cancer (Version Date 02/12/26)

IV Continuing Review

10355, A phase I study of DS-8201a in combination with olaparib in HER2-expressing malignancies (Version Date 10/24/25)

V Continuing Review

10629, A Phase I Dose Finding and Phase II Randomized Trial of Iadademstat Combined with Immune Checkpoint Inhibition Maintenance After Initial Chemoimmunotherapy in Patients with Extensive-Stage Small Cell Lung Cancer (Version Date 01/21/26)

VI Continuing Review

10590, NORM: Nodular Lymphocyte-predominant Hodgkin Lymphoma Patients Treated in a Randomized Phase 2 Trial with Either Rituximab or Mosunetuzumab (Version Date 06/10/25)

VII Continuing Review

10505, A Phase 1 and Randomized Phase 2 Trial of Selinexor and Temozolomide in Recurrent Glioblastoma (Version Date 01/26/26)

VIII Continuing Review

S1318, A Phase 2 Study of Blinatumomab and POMP (Prednisone, Vincristine, Methotrexate, 6-Mercaptopurine) for Patients \geq 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Negative (Ph-) Acute Lymphoblastic Leukemia (ALL) and of Dasatinib, Prednisone and Blinatumomab for Patients \geq 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Positive (Ph+) ALL, Relapsed/Refractory Ph+ ALL, and Philadelphia-Chromosome-Like Signature (Ph-Like) ALL (Newly Diagnosed or Relapsed/Refractory) with Known or Presumed Activating Dasatinib-Sensitive Mutations or Kinase Fusions (DSMKF) (Version Date 01/08/26)
